UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,429	06/15/2000	Raymond Paul Goodrich JR.	27-98B	1651

23713 7590 04/05/2005

GREENLEE WINNER AND SULLIVAN P C
4875 PEARL EAST CIRCLE
SUITE 200
BOULDER, CO 80301

EXAMINER	
CHORBAJI, MONZER R	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/596,429	GOODRICH ET AL.	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This non-final rejection is in response to the Remarks received on 01/14/2005

Remarks

1. The affidavit received on 01/14/2005 has been accepted. As a result, the 102 (e) and 103 (a) rejections are withdrawn.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

3. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

4. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-77, 104-105 and 107-108 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,258,577 in view of Goodrich, Jr. et al (U.S.P.N. 6,277,337).

With respect to claims 1, 50, 59, 68, 104 and 107, claim 1 of the ('577) reference teaches a method of inactivating a fluid (including blood constituents such as platelets) containing microorganisms by adding a certain amount of an endogenous photosensitizer then exposing the fluid along with the

photosensitizer to a photoradiation source in order to activate the photosensitizer and inactivate the microorganisms. However, with respect to claims 1, 50, 59, 68, 104 and 107 the claims of the ('577) reference fails to teach the step of adjusting the percentage of plasma in the fluid to a desired value such as the fluid contains a plasma content of between about 0% to about 50%. More specifically, the ('577) reference fails to teach the steps of mixing the photosensitizer along with the fluid and placing the fluid in a photopermeable container as disclosed in claims 1, 50 and 104. The ('337) reference teaches mixing the photosensitizer along with the fluid (col.24, lines 59-61) and placing the fluid in a photopermeable container (col.25, lines 13-15) such that the cuvette is photopermeable (col.17, lines 39-40). In addition, the ('337) reference teaches adjusting the plasma (bilirubin) content to about 30% of the total volume (col.24, lines 51-61). The 30% volume is based on 70:30 volume-to-volume ratios for a total volume of 100 ml. Furthermore, the ('337) reference teaches (col.24, lines 49-62) adding the stock solution to a solution containing plasma only (100% content of plasma in the fluid). Thus, it would have obvious to one having ordinary skill in the art at the time the invention was made to modify the method of claims of U.S. Patent No. 6,258,577 to include a plasma adjustment step in order to examine the impact of the plasma adjustment step on the platelet quality post-treatment ('337, col.23, lines 19-21).

With respect to claims 15-17, 20-21, 26, 31, 34, 43-45, 54, 62 and 70, claims 1-2, 3, 10, 4-5, 11, 6 and 8-9 of the ('577) reference teaches the following: photocatalytic products of the photosensitizer produces no toxicity to humans,

photosensitizer is 7,8-dimethyl-10-ribityl isoalloxazine, microorganisms are viruses, photoradiation is light in the visible or ultraviolet spectrums, photoradiation is of sufficient wavelength to activate 7,8-dimethyl-10-ribityl isoalloxazine in the fluid, photosensitizer is added to anticoagulant and the anticoagulant is added to the fluid, flowing the fluid past a source of photoradiation at a rate and depth selected to ensure penetration of the photoradiation through the fluid, fluid includes blood constituents, fluid includes whole blood and the fluid includes a separated blood product.

With respect to claims 2, 4-5 and 13, the claims of the ('577) fails to teach the following: mixing step occurs after the adjusting step, adjusting and mixing steps occur simultaneously, adjusting includes adding a diluting solution to achieve the desired percentage of plasma and adjusting step includes washing the fluid. The ('337) reference teaches the following: mixing step occurs after adjusting step (col.24, lines 51-52 and lines 60-62), both steps occur simultaneously (col.23, lines 29-33), diluting solution to a desired concentration of plasma (col.24, lines 60-62) and adjusting step includes washing the fluid (col.24, lines 60-62). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of claims of U.S. Patent No. 6,258,577 to include to include a plasma adjustment step in order to examine the impact of the plasma adjustment step on the platelet quality post-treatment ('337, col.23, lines 19-21).

With respect to claims 3 and 39, the claims of the ('577) fail to teach adjusting the percentage of the plasma occurring after mixing (i.e., placing). The

('337) reference adjusts the plasma content either before adding the photosensitizer or while adding the photosensitizer, but fails to disclose adjusting the plasma content after adding the photosensitizer. However, the ('337) reference teaches diluting the plasma content (col.13, lines 18-19) such that it would be obvious to one having ordinary skill in the art to modify the method of claims of U.S. Patent No. 6,258,577 by adjusting the plasma either before or after the addition of the photosensitizer in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claim 14, the claims of the ('577) fail to teach a plurality of washing steps. The ('337) reference teaches washing or reducing the content of the plasma (col.13, lines 18-19). However, it would be obvious to one having ordinary skill in the art to modify the method of claims of U.S. Patent No. 6,258,577 by washing the plasma as many times as required in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claims 6-12, the claims of the ('577) fail to teach the following: diluting solution is saline, diluting solution is a buffer, diluting solution includes nutrients, diluting solution includes phosphate, diluting solution is a cell storage solution, diluting solution is an anticoagulant and the diluting solution is a cryoperservative solution. With respect to claims 6-12, the ('337) reference teaches the following: diluting solution is saline (col.13, line 13), diluting solution is a buffer (col.13, line 13), diluting solution includes nutrients (col.13, lines 16-

19), diluting solution includes phosphate (col.13, lines 27-28), diluting solution is a cell storage solution (col.13, lines 16-19), diluting solution is an anticoagulant (col.12, lines 45-46) and the diluting solution is a cryoperservative solution (col.13, lines 25-29). Thus, it would be obvious to one having ordinary skill in the art to modify the method of claims of U.S. Patent No. 6,258,577 by including any of the solutions as taught by the ('337) reference since these solutions are useful as carriers for platelet concentrations to allow maintenance of cell quality and metabolism during storage (col.13, lines 16-19).

With respect to claims 18-19, the claims of the ('577) fail to teach the microorganisms are bacteria and HIV viruses. However, the ('337) reference teaches that the microorganisms are bacteria (col.4, line 15) and HIV viruses (col.4, line 17). Thus, it would be obvious to one having ordinary skill in the art to modify the method of claims of U.S. Patent No. 6,258,577 to include bacteria and HIV viruses as taught by the ('337) reference since HIV virus is a worldwide epidemic.

With respect to claims 22-23, the claims of the ('577) fail to teach that photoradiation is both in the visible and ultraviolet spectra and half the light is in the visible spectrum and about half the light is in the ultraviolet spectrum. The ('337) reference teaches that photoradiation is both in the visible (col.8, lines 64-65) and the ultraviolet spectra (col.8, lines 64-66) and half the light is in the visible spectrum and about half the light is in the ultraviolet spectrum (col.8, lines 66-67). Thus, it would be obvious to one having ordinary skill in the art to modify the method of claims of U.S. Patent No. 6,258,577 to include a mixture of visible

and ultraviolet spectra as taught by the ('337) reference since visible spectrum does not damage platelets but reduces the amount of the more harmful ultraviolet radiation required (col.9, lines 1-4).

With respect to claims 24-25, the claims of the ('577) fail to teach that one third or two thirds are in the visible spectrum and one or two thirds are in the ultraviolet spectrum. The ('337) reference teaches that other ratios of visible and ultraviolet spectra can be used (col.9, lines 1-2). Thus, it would be obvious to one having ordinary skill in the art to modify the method of claims of U.S. Patent No. 6,258,577 to use various ratios of the visible and ultraviolet light as taught by the ('337) reference since visible spectrum does not damage platelets but reduces the amount of the more harmful ultraviolet radiation required (col.9, lines 1-4).

With respect to claims 27-30, 51-52, 60-61 and 69, the claims of the ('577) fail to teach adjusting the content of the plasma; however, the ('337) reference adjusts the plasma content to about 30% of the total volume (col.24, lines 60-62) of plasma but fails to disclose adjusting the plasma content to other values. As a result, it would be obvious to one having ordinary skill in the art to modify the method of claims of U.S. Patent No. 6,258,577 by adjusting the content of the plasma as taught by the ('337) reference to various contents since adjusting the plasma content to other concentration values is a matter of routine experimentation.

With respect to claims 32-33 and 75-76, the claims of the ('577) fail to teach the addition of an enhancer and therapeutic protein to the fluid; however, the ('337) reference teaches the following: an enhancer such as adenine (col.10,

lines 1-5) is added to fluid prior to photoradiation of the fluid (col.10, lines 1-5) since the reference goal is to prevent damage of fluid from irradiation and adding a therapeutic protein (col.4, lines 44-46) such as factor VIII (col.4, line 46). So, it would be obvious to one having ordinary skill in the art to modify the method of claims of U.S. Patent No. 6,258,577 by adding enhancers as taught by the ('337) reference in order to prevent damage to desired fluid components (col.10, lines 2-4).

With respect to claims 35-37, the claims of the ('577) fail to teach the following: fluid and photosensitizer are contained in a transparent container, agitating the container during the exposing step, placing fluid in the container then adding the photosensitizer in powder form then agitating the container. The ('337) reference teaches the following: fluid and photosensitizer are contained in a transparent container (col.9, lines 52-58), agitating the container during the exposing step (col.9, lines 57-61), placing fluid in the container then adding the photosensitizer in powder form then agitating the container (col.24, lines 60-62 and lines col.25, lines 13-15). Thus, it would be obvious to one having ordinary skill in the art to modify the method of claims of U.S. Patent No. 6,258,577 by including an agitation step as taught by the ('337) reference in order to adequately expose all the fluid to the photoradiation to ensure inactivation of microorganisms (col.9, lines 57-61).

With respect to claims 38 and 40, the claims of the ('577) fail to teach adjusting the percentage content of the plasma; however, the ('337) reference teaches adjusting the percentage of plasma before placing fluid in the container

(col.24, lines 60-62 and lines col.25, lines 13-15) and the plasma is adjusted simultaneously with placing fluid in container (col.23, lines 29-35). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of U.S. Patent No. 6,258,577 by either adjusting the percentage of plasma before placing fluid or simultaneously with placing fluid in container as taught by the ('337) reference in order to examine the impact of sample processing conditions on the platelet quality post-treatment (col.23, lines 19-21).

With respect to claims 41-42, 105 and 108, the claims of the ('577) fail to teach adding nutrients in powder form such that the nutrients and photosensitizers are present in the container prior to addition of the fluid and a blood product that includes inactivated microorganisms, endogenous photosensitizer and a lowered plasma content than occurs naturally; however, the ('337) reference teaches adding nutrients (col.13, lines 16-19) such that whether nutrients are in powder or liquid forms is a matter of choice of design. Also, the ('337) reference teaches that nutrients and photosensitizers are present (col.13, lines 19-23) in the container prior to addition of the fluid (col.18, lines 42-44) and a blood product (col.10, lines 11-16) that includes inactivated microorganisms, endogenous photosensitizer and lowered plasma content than occurs naturally (col.13, lines 18-19). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of U.S. Patent No. 6,258,577 by placing nutrients and photosensitizer in the container prior to the addition of the fluid since the ('337) reference teaches both alternatives of placing photosensitizer in the already present fluid then irradiating or adding the fluid to

an already present photosensitizer in the container then irradiating since choosing either alternative is a matter of choice of design.

With respect to claims 46-49, the claims of the ('577) fail to teach the following: the fluid consists essentially of platelets, the fluid consists essentially of serum, the fluid consists essentially of plasma and the fluid consists essentially of red blood cells. The ('337) reference teaches the following: the fluid consists essentially of platelets (col.24, lines 51-52), the fluid consists essentially of serum (col.4, lines 42-43), the fluid consists essentially of plasma (col.4, line 32) and the fluid consists essentially of red blood cells (col.4, lines 41-42). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of U.S. Patent No. 6,258,577 by irradiating various separated blood constituents as taught by the ('337) reference since such constituents can be decontaminated with viruses (col.4, lines 34-37).

With respect to claims 53 and 77, the claims of the ('577) fail to teach adding additives so that proteins remains biologically active after the irradiation step; however, the ('337) reference teaches adding additives such that damage due to irradiation is prevented to desired components (col.10, lines 1-4 and col.3, lines 64-67). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of U.S. Patent No. 6,258,577 by adding additives to the fluid to be irradiated as taught by the ('337) reference since such additives maintains biological activities of proteins (col.3, lines 64-67 and col.10, lines 1-4).

With respect to claims 55, 63-64 and 71, the claims of the ('577) fail to teach concentration values for the photosensitizer; however, the ('337) reference teaches that the concentration of the photosensitizer is between about 1 to about 200 micromolar (col.24, lines 61-63). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of U.S. Patent No. 6,258,577 by adding any amount of the photosensitizer within the range disclosed in the ('337) reference since choosing any amount is a matter of routine experimentation (col.13, lines 19-23).

With respect to claims 56-58, 65-67 and 72-74, the claims of the ('577) fail to teach wavelength and energy values for the photoradiation; however, the ('337) reference teaches the following: photoradiation is between about 400 and about 500 nm (col.8, line 62), photoradiation is between about 100 and about 500 j / cm^2 (col.8, line 61) and photoradiation is between about 100 and about 200 nm (col.9, lines 49-50). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of U.S. Patent No. 6,258,577 by irradiating biological fluids at the wavelength and energy ranges disclosed in the ('337) reference in order to activate the photosensitizer (col.8, lines 50-53).

6. Claims 1-77, 104-105 and 107-108 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-6, 29 and 32 of copending Application No. 09/962,029 in view of Goodrich, Jr. et al (U.S.P.N. 6,277,337).

This is a provisional obviousness-type double patenting rejection.

With respect to claims 1, 50, 59, 68, 104 and 107, claims 1, 3-6, 29 and 32 of copending Application No. 09/962,029 teaches a method for inactivating pathogens in a blood product including the addition of a photosensitizer to a blood thereby forming a mixture then exposing the mixture to pulses of light. However, the claims 1, 3-6, 29 and 32 of copending Application No. 09/962,029 fail to teach placing the fluid in a photopermeable container and adjusting the percentage of plasma in the fluid to a desired value such as the fluid contains a plasma content of between about 0% to about 50%. The ('337) reference teaches placing the fluid in a photopermeable container (col.25, lines 13-15) such that the cuvette is photopermeable (col.17, lines 39-40). In addition, the ('337) reference teaches adjusting the plasma (bilirubin) content to about 30% of the total volume (col.24, lines 51-61). The 30% volume is based on 70:30 volume-to-volume ratios for a total volume of 100 ml. Furthermore, the ('337) reference teaches (col.24, lines 49-62) adding the stock solution to a solution containing plasma only (100% content of plasma in the fluid). Thus, it would have obvious to one having ordinary skill in the art at the time the invention was made to modify the method claims of copending Application No. 09/962,029 to include a plasma adjustment step in order to examine the impact of the plasma adjustment step on the platelet quality post-treatment ('337, col.23, lines 19-21).

With respect to claims 2, 4-5 and 13, the claims of copending Application No. 09/962,029 fail to teach the following: mixing step occurs after the adjusting step, adjusting and mixing steps occur simultaneously, adjusting includes adding a diluting solution to achieve the desired percentage of plasma and adjusting

step includes washing the fluid. The ('337) reference teaches the following: mixing step occurs after adjusting step (col.24, lines 51-52 and lines 60-62), both steps occur simultaneously (col.23, lines 29-33), diluting solution to a desired concentration of plasma (col.24, lines 60-62) and adjusting step includes washing the fluid (col.24, lines 60-62). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the claims of copending Application No. 09/962,029 to include to include a plasma adjustment step in order to examine the impact of the plasma adjustment step on the platelet quality post-treatment ('337, col.23, lines 19-21).

With respect to claims 3 and 39, the claims of copending Application No. 09/962,029 fail to teach adjusting the percentage of the plasma occurring after mixing (i.e., placing). The ('337) reference adjusts the plasma content either before adding the photosensitizer or while adding the photosensitizer, but fails to disclose adjusting the plasma content after adding the photosensitizer. However, the ('337) reference teaches diluting the plasma content (col.13, lines 18-19) such that it would be obvious to one having ordinary skill in the art to modify the method of the claims of copending Application No. 09/962,029 by adjusting the plasma either before or after the addition of the photosensitizer in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claim 14, the claims of copending Application No. 09/962,029 fail to teach a plurality of washing steps. The ('337) reference teaches washing or reducing the content of the plasma (col.13, lines 18-19).

However, it would be obvious to one having ordinary skill in the art to modify the method of the claims of copending Application No. 09/962,029 by washing the plasma as many times as required in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claims 6-12, the claims of copending Application No. 09/962,029 fail to teach the following: diluting solution is saline, diluting solution is a buffer, diluting solution includes nutrients, diluting solution includes phosphate, diluting solution is a cell storage solution, diluting solution is an anticoagulant and the diluting solution is a cryoperservative solution. With respect to claims 6-12, the ('337) reference teaches the following: diluting solution is saline (col.13, line 13), diluting solution is a buffer (col.13, line 13), diluting solution includes nutrients (col.13, lines 16-19), diluting solution includes phosphate (col.13, lines 27-28), diluting solution is a cell storage solution (col.13, lines 16-19), diluting solution is an anticoagulant (col.12, lines 45-46) and the diluting solution is a cryoperservative solution (col.13, lines 25-29). Thus, it would be obvious to one having ordinary skill in the art to modify the method of the claims of copending Application No. 09/962,029 by including any of the solutions as taught by the ('337) reference since these solutions are useful as carriers for platelet concentrations to allow maintenance of cell quality and metabolism during storage (col.13, lines 16-19).

With respect to claims 15-19, 26, 54, 62 and 70, the claims of copending Application No. 09/962,029 fail the following: the photosensitizer is of low toxicity

to humans, the photosensitizer is 7,8-dimethyl-10-ribityl isoalloxazine and the microorganisms are bacteria and HIV viruses. However, the ('337) reference teaches the following: the photosensitizer is of low toxicity to humans (abstract, lines 5-6), the photosensitizer is 7,8-dimethyl-10-ribityl isoalloxazine (col.13, line 28) and the microorganisms are bacteria (col.4, line 15) and HIV viruses (col.4, line 17). Thus, it would be obvious to one having ordinary skill in the art to modify the method of the claims of copending Application No. 09/962,029 to include bacteria and HIV viruses as taught by the ('337) reference since HIV virus is a worldwide epidemic.

With respect to claims 20-23, the claims of copending Application No. 09/962,029 fail to teach the following: photoradiation is in the visible spectrum, photoradiation is in the ultraviolet spectrum, photoradiation is both in the visible and ultraviolet spectra and half the light is in the visible spectrum and about half the light is in the ultraviolet spectrum. The ('337) reference teaches the following: photoradiation is in the visible spectrum (col.8, lines 64-65), photoradiation is in the ultraviolet spectrum (col.8, lines 64-65), photoradiation is both in the visible (col.8, lines 64-65) and the ultraviolet spectra (col.8, lines 64-66) and half the light is in the visible spectrum and about half the light is in the ultraviolet spectrum (col.8, lines 66-67). Thus, it would be obvious to one having ordinary skill in the art to modify the method of the claims of copending Application No. 09/962,029 to include a mixture of visible and ultraviolet spectra as taught by the ('337) reference since visible spectrum does not damage platelets but reduces the amount of the more harmful ultraviolet radiation required (col.9, lines 1-4).

With respect to claims 24-25, the claims of copending Application No. 09/962,029 fail to teach that one third or two thirds are in the visible spectrum and one or two thirds are in the ultraviolet spectrum. The ('337) reference teaches that other ratios of visible and ultraviolet spectra can be used (col.9, lines 1-2). Thus, it would be obvious to one having ordinary skill in the art to modify the method of the claims of copending Application No. 09/962,029 to use various ratios of the visible and ultraviolet light as taught by the ('337) reference since visible spectrum does not damage platelets but reduces the amount of the more harmful ultraviolet radiation required (col.9, lines 1-4).

With respect to claims 27-30, 51-52, 60-61 and 69, the claims of copending Application No. 09/962,029 fail to teach adjusting the content of the plasma; however, the ('337) reference adjusts the plasma content to about 30% of the total volume (col.24, lines 60-62) of plasma but fails to disclose adjusting the plasma content to other values. As a result, it would be obvious to one having ordinary skill in the art to modify the method of the claims of copending Application No. 09/962,029 by adjusting the content of the plasma as taught by the ('337) reference to various contents since adjusting the plasma content to other concentration values is a matter of routine experimentation.

With respect to claims 31-33 and 75-76, the claims of copending Application No. 09/962,029 fail to teach the following: adding photosensitizer to anticoagulant then adding the anticoagulant to fluid, addition of an enhancer and addition of therapeutic protein to the fluid; however, the ('337) reference teaches the following: adding photosensitizer to anticoagulant then adding the

anticoagulant to fluid (col.9, lines 65-67), addition an enhancer such as adenine (col.10, lines 1-5) is added to fluid prior to photoradiation of the fluid (col.10, lines 1-5) since the reference goal is to prevent damage of fluid from irradiation and adding a therapeutic protein (col.4, lines 44-46) such as factor VIII (col.4, line 46). So, it would be obvious to one having ordinary skill in the art to modify the method of claims of copending Application No. 09/962,029 by adding enhancers as taught by the ('337) reference in order to prevent damage to desired fluid components (col.10, lines 2-4).

With respect to claims 34-37, the claims of copending Application No. 09/962,029 fail to teach the following: flowing the fluid containing photosensitizer past a source of photoradiation at a rate and depth to ensure penetration of the photoradiation, fluid and photosensitizer are contained in a transparent container, agitating the container during the exposing step, placing fluid in the container then adding the photosensitizer in powder form then agitating the container. The ('337) reference teaches the following: flowing the fluid containing photosensitizer past a source of photoradiation (col.9, lines 51-56) at a rate (figure 7, 184) and depth (figure 7, d) to ensure penetration of the photoradiation (col., fluid and photosensitizer are contained in a transparent container (col.9, lines 52-58), agitating the container during the exposing step (col.9, lines 57-61), placing fluid in the container then adding the photosensitizer in powder form then agitating the container (col.24, lines 60-62 and lines col.25, lines 13-15). Thus, it would be obvious to one having ordinary skill in the art to modify the method of claims of copending Application No. 09/962,029 by including an agitation step as taught by

the ('337) reference in order to adequately expose all the fluid to the photoradiation to ensure inactivation of microorganisms (col.9, lines 57-61).

With respect to claims 38 and 40, the claims of copending Application No. 09/962,029 fail to teach adjusting the percentage content of the plasma; however, the ('337) reference teaches adjusting the percentage of plasma before placing fluid in the container (col.24, lines 60-62 and lines col.25, lines 13-15) and the plasma is adjusted simultaneously with placing fluid in container (col.23, lines 29-35). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of copending Application No. 09/962,029 by either adjusting the percentage of plasma before placing fluid or simultaneously with placing fluid in container as taught by the ('337) reference in order to examine the impact of sample processing conditions on the platelet quality post-treatment (col.23, lines 19-21).

With respect to claims 41-42, 105 and 108, the claims of copending Application No. 09/962,029 fail to teach adding nutrients in powder form such that the nutrients and photosensitizers are present in the container prior to addition of the fluid and a blood product that includes inactivated microorganisms, endogenous photosensitizer and a lowered plasma content than occurs naturally; however, the ('337) reference teaches adding nutrients (col.13, lines 16-19) such that whether nutrients are in powder or liquid forms is a matter of choice of design. Also, the ('337) reference teaches that nutrients and photosensitizers are present (col.13, lines 19-23) in the container prior to addition of the fluid (col.18, lines 42-44) and a blood product (col.10, lines 11-16) that

includes inactivated microorganisms, endogenous photosensitizer and lowered plasma content than occurs naturally (col.13, lines 18-19). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of copending Application No. 09/962,029 by placing nutrients and photosensitizer in the container prior to the addition of the fluid since the ('337) reference teaches both alternatives of placing photosensitizer in the already present fluid then irradiating or adding the fluid to an already present photosensitizer in the container then irradiating since choosing either alternative is a matter of choice of design.

With respect to claims 43-49, the claims of copending Application No. 09/962,029 fail to teach the following: the fluid includes blood constituents, the fluid includes whole blood, the fluid includes a separated blood product, the fluid consists essentially of platelets, the fluid consists essentially of serum, the fluid consists essentially of plasma and the fluid consists essentially of red blood cells. The ('337) reference teaches the following: the fluid includes blood constituents (abstract, lines 2-3), the fluid includes whole blood (col.4, line 39), the fluid includes a separated blood product (col.4, lines 41-43), the fluid consists essentially of platelets (col.24, lines 51-52), the fluid consists essentially of serum (col.4, lines 42-43), the fluid consists essentially of plasma (col.4, line 32) and the fluid consists essentially of red blood cells (col.4, lines 41-42). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of copending Application No. 09/962,029 by irradiating various separated

blood constituents as taught by the ('337) reference since such constituents can be decontaminated with viruses (col.4, lines 34-37).

With respect to claims 53 and 77, the claims of copending Application No. 09/962,029 fail to teach adding additives so that proteins remains biologically active after the irradiation step; however, the ('337) reference teaches adding additives such that damage due to irradiation is prevented to desired components (col.10, lines 1-4 and col.3, lines 64-67). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of copending Application No. 09/962,029 by adding additives to the fluid to be irradiated as taught by the ('337) reference since such additives maintains biological activities of proteins (col.3, lines 64-67 and col.10, lines 1-4).

With respect to claims 55, 63-64 and 71, the claims of copending Application No. 09/962,029 fail to teach concentration values for the photosensitizer; however, the ('337) reference teaches that the concentration of the photosensitizer is between about 1 to about 200 micromolar (col.24, lines 61-63). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of copending Application No. 09/962,029 by adding any amount of the photosensitizer within the range disclosed in the ('337) reference since choosing any amount is a matter of routine experimentation (col.13, lines 19-23).

With respect to claims 56-58, 65-67 and 72-74, the claims of copending Application No. 09/962,029 fail to teach wavelength and energy values for the photoradiation; however, the ('337) reference teaches the following:

photoradiation is between about 400 and about 500 nm (col.8, line 62), photoradiation is between about 100 and about 500 j / cm^2 (col.8, line 61) and photoradiation is between about 100 and about 200 nm (col.9, lines 49-50). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of copending Application No. 09/962,029 by irradiating biological fluids at the wavelength and energy ranges disclosed in the ('337) reference in order to activate the photosensitizer (col.8, lines 50-53).

7. Claims 1-77, 104-105 and 107-108 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 and 31-38 of copending Application No. 10/357,599 in view of Goodrich, Jr. et al (U.S.P.N. 6,277,337).

This is a provisional obviousness-type double patenting rejection.

With respect to claims 1, 50, 59, 68, 104 and 107, claims 1-11 and 31-38 of copending Application No. 10/357,599 teach a method for inactivating pathogens in a fluid containing blood product including the addition of a photosensitizer to a blood thereby forming a mixture then irradiating the mixture with pulses of light. However, the claims 1-11 and 31-38 of copending Application No. 10/357,599 fail to teach placing the fluid in a photopermeable container and adjusting the percentage of plasma in the fluid to a desired value such as the fluid contains a plasma content of between about 0% to about 50%. The ('337) reference teaches placing the fluid in a photopermeable container (col.25, lines 13-15) such that the cuvette is photopermeable (col.17, lines 39-40). In addition, the ('337) reference teaches adjusting the plasma (bilirubin) content to about

30% of the total volume (col.24, lines 51-61). The 30% volume is based on 70:30 volume-to-volume ratios for a total volume of 100 ml. Furthermore, the ('337) reference teaches (col.24, lines 49-62) adding the stock solution to a solution containing plasma only (100% content of plasma in the fluid). Thus, it would have obvious to one having ordinary skill in the art at the time the invention was made to modify the method claims of copending Application No. 10/357,599 to include a plasma adjustment step in order to examine the impact of the plasma adjustment step on the platelet quality post-treatment ('337, col.23, lines 19-21).

With respect to claims 2, 4-5 and 13, the claims of copending Application No. 10/357,599 fail to teach the following: mixing step occurs after the adjusting step, adjusting and mixing steps occur simultaneously, adjusting includes adding a diluting solution to achieve the desired percentage of plasma and adjusting step includes washing the fluid. The ('337) reference teaches the following: mixing step occurs after adjusting step (col.24, lines 51-52 and lines 60-62), both steps occur simultaneously (col.23, lines 29-33), diluting solution to a desired concentration of plasma (col.24, lines 60-62) and adjusting step includes washing the fluid (col.24, lines 60-62). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the claims of copending Application No. 10/357,599 to include to include a plasma adjustment step in order to examine the impact of the plasma adjustment step on the platelet quality post-treatment ('337, col.23, lines 19-21).

With respect to claims 3 and 39, the claims of copending Application No. 10/357,599 fail to teach adjusting the percentage of the plasma occurring after

mixing (i.e., placing). The ('337) reference adjusts the plasma content either before adding the photosensitizer or while adding the photosensitizer, but fails to disclose adjusting the plasma content after adding the photosensitizer. However, the ('337) reference teaches diluting the plasma content (col.13, lines 18-19) such that it would be obvious to one having ordinary skill in the art to modify the method of the claims of copending Application No. 10/357,599 by adjusting the plasma either before or after the addition of the photosensitizer in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claim 14, the claims of copending Application No. 10/357,599 fail to teach a plurality of washing steps. The ('337) reference teaches washing or reducing the content of the plasma (col.13, lines 18-19). However, it would be obvious to one having ordinary skill in the art to modify the method of the claims of copending Application No. 10/357,599 by washing the plasma as many times as required in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claims 6-12, the claims of copending Application No. 10/357,599 fail to teach the following: diluting solution is saline, diluting solution is a buffer, diluting solution includes nutrients, diluting solution includes phosphate, diluting solution is a cell storage solution, diluting solution is an anticoagulant and the diluting solution is a cryoperservative solution. With respect to claims 6-12, the ('337) reference teaches the following: diluting

solution is saline (col.13, line 13), diluting solution is a buffer (col.13, line 13), diluting solution includes nutrients (col.13, lines 16-19), diluting solution includes phosphate (col.13, lines 27-28), diluting solution is a cell storage solution (col.13, lines 16-19), diluting solution is an anticoagulant (col.12, lines 45-46) and the diluting solution is a cryoperservative solution (col.13, lines 25-29). Thus, it would be obvious to one having ordinary skill in the art to modify the method of the claims of copending Application No. 10/357,599 by including any of the solutions as taught by the ('337) reference since these solutions are useful as carriers for platelet concentrations to allow maintenance of cell quality and metabolism during storage (col.13, lines 16-19).

With respect to claims 15-19, 26, 54, 62 and 70, the claims of copending Application No. 10/357,599 fail the following: the photosensitizer is of low toxicity to humans, the photosensitizer is 7,8-dimethyl-10-ribityl isoalloxazine and the microorganisms are bacteria and HIV viruses. However, the ('337) reference teaches the following: the photosensitizer is of low toxicity to humans (abstract, lines 5-6), the photosensitizer is 7,8-dimethyl-10-ribityl isoalloxazine (col.13, line 28) and the microorganisms are bacteria (col.4, line 15) and HIV viruses (col.4, line 17). Thus, it would be obvious to one having ordinary skill in the art to modify the method of the claims of copending Application No. 10/357,599 to include bacteria and HIV viruses as taught by the ('337) reference since HIV virus is a worldwide epidemic.

With respect to claims 20-23, the claims of copending Application No. 10/357,599 fail to teach the following: photoradiation is in the visible spectrum,

photoradiation is in the ultraviolet spectrum, photoradiation is both in the visible and ultraviolet spectra and half the light is in the visible spectrum and about half the light is in the ultraviolet spectrum. The ('337) reference teaches the following: photoradiation is in the visible spectrum (col.8, lines 64-65), photoradiation is in the ultraviolet spectrum (col.8, lines 64-65), photoradiation is both in the visible (col.8, lines 64-65) and the ultraviolet spectra (col.8, lines 64-66) and half the light is in the visible spectrum and about half the light is in the ultraviolet spectrum (col.8, lines 66-67). Thus, it would be obvious to one having ordinary skill in the art to modify the method of the claims of copending Application No. 10/357,599 to include a mixture of visible and ultraviolet spectra as taught by the ('337) reference since visible spectrum does not damage platelets but reduces the amount of the more harmful ultraviolet radiation required (col.9, lines 1-4).

With respect to claims 24-25, the claims of copending Application No. 10/357,599 fail to teach that one third or two thirds are in the visible spectrum and one or two thirds are in the ultraviolet spectrum. The ('337) reference teaches that other ratios of visible and ultraviolet spectra can be used (col.9, lines 1-2). Thus, it would be obvious to one having ordinary skill in the art to modify the method of the claims of copending Application No. 10/357,599 to use various ratios of the visible and ultraviolet light as taught by the ('337) reference since visible spectrum does not damage platelets but reduces the amount of the more harmful ultraviolet radiation required (col.9, lines 1-4).

With respect to claims 27-30, 51-52, 60-61 and 69, the claims of copending Application No. 10/357,599 fail to teach adjusting the content of the

plasma; however, the ('337) reference adjusts the plasma content to about 30% of the total volume (col.24, lines 60-62) of plasma but fails to disclose adjusting the plasma content to other values. As a result, it would be obvious to one having ordinary skill in the art to modify the method of the claims of copending Application No. 10/357,599 by adjusting the content of the plasma as taught by the ('337) reference to various contents since adjusting the plasma content to other concentration values is a matter of routine experimentation.

With respect to claims 31-33 and 75-76, the claims of copending Application No. 10/357,599 fail to teach the following: adding photosensitizer to anticoagulant then adding the anticoagulant to fluid, addition of an enhancer and addition of therapeutic protein to the fluid; however, the ('337) reference teaches the following: adding photosensitizer to anticoagulant then adding the anticoagulant to fluid (col.9, lines 65-67), addition an enhancer such as adenine (col.10, lines 1-5) is added to fluid prior to photoradiation of the fluid (col.10, lines 1-5) since the reference goal is to prevent damage of fluid from irradiation and adding a therapeutic protein (col.4, lines 44-46) such as factor VIII (col.4, line 46). So, it would be obvious to one having ordinary skill in the art to modify the method of claims of copending Application No. 10/357,599 by adding enhancers as taught by the ('337) reference in order to prevent damage to desired fluid components (col.10, lines 2-4).

With respect to claims 34-37, the claims of copending Application No. 10/357,599 fail to teach the following: flowing the fluid containing photosensitizer past a source of photoradiation at a rate and depth to ensure penetration of the

photoradiation, fluid and photosensitizer are contained in a transparent container, agitating the container during the exposing step, placing fluid in the container then adding the photosensitizer in powder form then agitating the container. The ('337) reference teaches the following: flowing the fluid containing photosensitizer past a source of photoradiation (col.9, lines 51-56) at a rate (figure 7, 184) and depth (figure 7, d) to ensure penetration of the photoradiation (col., fluid and photosensitizer are contained in a transparent container (col.9, lines 52-58), agitating the container during the exposing step (col.9, lines 57-61), placing fluid in the container then adding the photosensitizer in powder form then agitating the container (col.24, lines 60-62 and lines col.25, lines 13-15). Thus, it would be obvious to one having ordinary skill in the art to modify the method of claims of copending Application No. 10/357,599 by including an agitation step as taught by the ('337) reference in order to adequately expose all the fluid to the photoradiation to ensure inactivation of microorganisms (col.9, lines 57-61).

With respect to claims 38 and 40, the claims of copending Application No. 10/357,599 fail to teach adjusting the percentage content of the plasma; however, the ('337) reference teaches adjusting the percentage of plasma before placing fluid in the container (col.24, lines 60-62 and lines col.25, lines 13-15) and the plasma is adjusted simultaneously with placing fluid in container (col.23, lines 29-35). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of copending Application No. 10/357,599 by either adjusting the percentage of plasma before placing fluid or simultaneously with placing fluid in container as taught by the ('337) reference in order to

examine the impact of sample processing conditions on the platelet quality post-treatment (col.23, lines 19-21).

With respect to claims 41-42, 105 and 108, the claims of copending Application No. 10/357,599 fail to teach adding nutrients in powder form such that the nutrients and photosensitizers are present in the container prior to addition of the fluid and a blood product that includes inactivated microorganisms, endogenous photosensitizer and a lowered plasma content than occurs naturally; however, the ('337) reference teaches adding nutrients (col.13, lines 16-19) such that whether nutrients are in powder or liquid forms is a matter of choice of design. Also, the ('337) reference teaches that nutrients and photosensitizers are present (col.13, lines 19-23) in the container prior to addition of the fluid (col.18, lines 42-44) and a blood product (col.10, lines 11-16) that includes inactivated microorganisms, endogenous photosensitizer and lowered plasma content than occurs naturally (col.13, lines 18-19). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of copending Application No. 10/357,599 by placing nutrients and photosensitizer in the container prior to the addition of the fluid since the ('337) reference teaches both alternatives of placing photosensitizer in the already present fluid then irradiating or adding the fluid to an already present photosensitizer in the container then irradiating since choosing either alternative is a matter of choice of design.

With respect to claims 43-49, the claims of copending Application No. 10/357,599 fail to teach the following: the fluid includes blood constituents, the

fluid includes whole blood, the fluid includes a separated blood product, the fluid consists essentially of platelets, the fluid consists essentially of serum, the fluid consists essentially of plasma and the fluid consists essentially of red blood cells. The ('337) reference teaches the following: the fluid includes blood constituents (abstract, lines 2-3), the fluid includes whole blood (col.4, line 39), the fluid includes a separated blood product (col.4, lines 41-43), the fluid consists essentially of platelets (col.24, lines 51-52), the fluid consists essentially of serum (col.4, lines 42-43), the fluid consists essentially of plasma (col.4, line 32) and the fluid consists essentially of red blood cells (col.4, lines 41-42). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of copending Application No. 10/357,599 by irradiating various separated blood constituents as taught by the ('337) reference since such constituents can be decontaminated with viruses (col.4, lines 34-37).

With respect to claims 53 and 77, the claims of copending Application No. 10/357,599 fail to teach adding additives so that proteins remains biologically active after the irradiation step; however, the ('337) reference teaches adding additives such that damage due to irradiation is prevented to desired components (col.10, lines 1-4 and col.3, lines 64-67). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of copending Application No. 10/357,599 by adding additives to the fluid to be irradiated as taught by the ('337) reference since such additives maintains biological activities of proteins (col.3, lines 64-67 and col.10, lines 1-4).

With respect to claims 55, 63-64 and 71, the claims of copending Application No. 10/357,599 fail to teach concentration values for the photosensitizer; however, the ('337) reference teaches that the concentration of the photosensitizer is between about 1 to about 200 micromolar (col.24, lines 61-63). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of copending Application No. 10/357,599 by adding any amount of the photosensitizer within the range disclosed in the ('337) reference since choosing any amount is a matter of routine experimentation (col.13, lines 19-23).

With respect to claims 56-58, 65-67 and 72-74, the claims of copending Application No. 10/357,599 fail to teach wavelength and energy values for the photoradiation; however, the ('337) reference teaches the following: photoradiation is between about 400 and about 500 nm (col.8, line 62), photoradiation is between about 100 and about 500 j / cm^2 (col.8, line 61) and photoradiation is between about 100 and about 200 nm (col.9, lines 49-50). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of claims of copending Application No. 10/357,599 by irradiating biological fluids at the wavelength and energy ranges disclosed in the ('337) reference in order to activate the photosensitizer (col.8, lines 50-53).

8. Claims 78-103 and 106 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-30 of copending Application No. 10/357,599 in view of Goodrich, Jr. et al (U.S.P.N. 6,277,337).

This is a provisional obviousness-type double patenting rejection.

With respect to claims 78, 84, 97-98 and 106, claims 12-30 of copending Application No. 10/357,599 teach a treatment chamber for inactivating pathogens in a blood product fluid and a photosensitizer including the following: at least one radiation source for irradiating the fluid, a support platform for holding the fluid to be irradiated (means for maintaining), a photopermeable container that includes both the fluid and the photosensitizer and a support platform moves in multiple directions (means for mixing or agitating). However, claims 12-30 of copending Application No. 10/357,599 fail to teach the following: a fluid in a container having a portion of the plasma removed, means for adjusting the plasma, a photopermeable container in fluid communication with the means for adding the photosensitizer and means for adjusting the plasma content and means for producing selected flow rate. With respect to claims 78, 84, 97-98 and 106, the ('337) reference teaches an apparatus for inactivating microorganisms in fluids (col.3, lines 59-65) including the following: adjusting (i.e., removing) the percentage of plasma or bilirubin (col.24, line 51), mixing (col.24, lines 56-58), exposing the fluid to photoradiation (col.24, lines 64-65), a source of light (figure 7, 160), means for maintaining the fluid in the light path (figure 7, 164 and col.17, lines 39-41), a container (figure 7, 164, col.13, lines 6-8, and col.24, line 51), means for adjusting the plasma content of the fluid (col.24, lines 49-52), means for mixing (figure 7, 186), a photopermeable container (figure 7, 164 and col.13, lines 18-19) in fluid communication with the means for adding the photosensitizer and means for adjusting the plasma content, means for producing selected flow

rate (figure 7, 184) and means for agitating the container (col.8, lines 34-36). Thus, it would have obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus claims of copending Application No. 10/357,599 to include means for adjusting the plasma content in order to examine the impact of the plasma adjustment step on the platelet quality post-treatment ('337, col.23, lines 19-21).

With respect to claims 80, 82 and 89-90, claims 12, 20 and 28-29 of copending Application No. 10/357,599 teaches the use of light emitting diodes, fluid includes blood components and the photoradiation includes a reflective surface as an enhancer.

With respect to claim 79, the claims of copending Application No. 10/357,599 fail to teach a support surface substantially parallel to the light source; however, the ('337) reference discloses a support surface substantially parallel to the source of light (figure 7, unlabeled bottom of container164). Thus, it would have obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus claims of copending Application No. 10/357,599 to include support surface substantially parallel to the light source as taught by the ('337) reference in order to ensure all the fluid have been irradiated.

With respect to claims 81 and 85-88, the claims of copending Application No. 10/357,599 fail to teach the following: light emitting diodes to emit light in the visible range spectrum, photoradiation source provides light in the visible spectrum, photoradiation source provides light in the ultraviolet spectrum and photoradiation source provides light in both the visible and the ultraviolet spectra.

The ('337) reference discloses the following: light emitting source to emit light in the visible range spectrum (col.8, lines 64-65), photoradiation source provides light in the visible spectrum (col.8, lines 64-65), photoradiation source provides light in the ultraviolet spectrum (col.8, line 63) and photoradiation source provides light in both the visible and the ultraviolet spectra (col.8, lines 64-66). Thus, it would have obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus claims of copending Application No. 10/357,599 by irradiating with both visible and ultraviolet spectra as taught by the ('337) reference since visible spectrum does not damage platelets but reduces the amount of the more harmful ultraviolet radiation required (col.9, lines 1-4).

With respect to claim 83, the claims of copending Application No. 10/357,599 fail to teach that the photosensitizer is 7,8-dimethyl-10-ribityl isoalloxazine; however, the ('337) reference discloses that the photosensitizer is 7,8-dimethyl-10-ribityl isoalloxazine (col.13, line 28). Thus, it would have obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus claims of copending Application No. 10/357,599 to include 7,8-dimethyl-10-ribityl isoalloxazine as taught by the ('337) reference since it is a non-toxic photosensitizer (abstract, lines 5-6).

With respect to claims 91-96, the claims of copending Application No. 10/357,599 fail to teach the following: a light guide for conducting photoradiation from the photoradiation source to the container (figure 7, 162), a temperature monitor (figure 7, 192), a temperature controller such as a fan (col.17, lines 41-43), means for flowing the fluid into and out of the container (figure 7, 170, 184,

186 and 188) and means for agitating the fluid. The ('337) reference teaches the following: a light guide for conducting photoradiation from the photoradiation source to the container, a temperature monitor, a temperature controller, a fan, means for flowing the fluid into and out of the container and means for agitating the fluid (col.9, line 57). Thus, it would have obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus claims of copending Application No. 10/357,599 to include agitating means as taught by the ('337) reference in order to adequately expose all the fluid to the photoradiation to ensure inactivation of microorganisms (col.9, lines 59-61).

With respect to claims 99-101, the claims of copending Application No. 10/357,599 fail to teach the following: the photopermeable container is a transparent plastic bag, the photopermeable container is a transparent rigid plastic container and the means for agitating includes a shaker table. The ('337) reference teaches the following: the photopermeable container is a transparent plastic bag (col.28, example 12), the photopermeable container is a transparent rigid plastic container (figure 7, 164) and the means for agitating includes a shaker table (col.9, line 57). Thus, it would have obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus claims of copending Application No. 10/357,599 to include a shaker table as taught by the ('337) reference in order to adequately expose all the fluid to the photoradiation to ensure inactivation of microorganisms (col.9, lines 59-61).

With respect to claims 102-103, the claims of copending Application No. 10/357,599 fail to teach that the container contains the photosensitizer prior to

addition of the fluid and means for adjusting the level of plasma in the fluid includes a suitable amount of solution contained in the container. The ('337) reference teaches that the container contains the photosensitizer prior to addition of the fluid (col.18, lines 42-44) and means for adjusting the level of plasma in the fluid includes a suitable amount of solution contained in the container (col.13, lines 18-19). Thus, it would have obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus claims of copending Application No. 10/357,599 to include means for adjusting the plasma content as taught by the ('337) reference in order to examine the impact of the plasma adjustment step on the platelet quality post-treatment ('337, col.23, lines 19-21).

Response to Arguments

9. Applicant's arguments with respect to claims 1-108 have been considered but are moot in view of the new ground(s) of rejection.

On pages 16-17, 19-20 of Remarks, applicant argues that the Obviousness-type Double Patenting Rejections over U.S. Patent No. 6,258,577 in view of U.S. Patent No. 6,277,337 is improper since such rejection is only limited to the scope of claims. The examiner disagrees since this rejection is an obviousness-Type. It involves analyzing the claims in a similar manner as set forth in the Graham v. John Deere Co. The first step is to determine the scope and content of a patent claim and the prior art relative to a claim in the application at issue. Thus, not only the scope of the claims can be applied but the prior art as well. Any part of the secondary reference can be applied to meet the limitations of the instant claims.

On pages 19-20 of Remarks section, applicant argues that the Provisional Obviousness-type Double Patenting Rejections over 09/962,029 in view of U.S. Patent No. 6,277,337 is improper since such rejection is only limited to the scope of claims. The examiner disagrees. See MPEP 8.37 Provision Rejection, Obviousness Type Double Patenting – with Secondary Reference. The same argument applies to the other Provisional Obviousness-type Double Patenting Rejections mentioned on page 20.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JOHN KIM can be reached on (571) 272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN KIM
SUPERVISORY EXAMINER
GROUP 1700

Monzer R. Chorbaji MRC
Patent Examiner
AU 1744
03/31/2005